

## **REMARKS**

Claims 1-34 are pending. Applicant addresses each of the rejections in the order in which they appear in the Action.

### **I. Section 102(b) Rejection Overcome**

Claims 1-5, 7-13, 27, and 28 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,292,966 to Mono *et al.* (Mono). Applicant respectfully traverses this rejection.

Claim 1 recites an oral inhaler suitable for delivering a pharmaceutical formulation to a patient, said inhaler comprising:

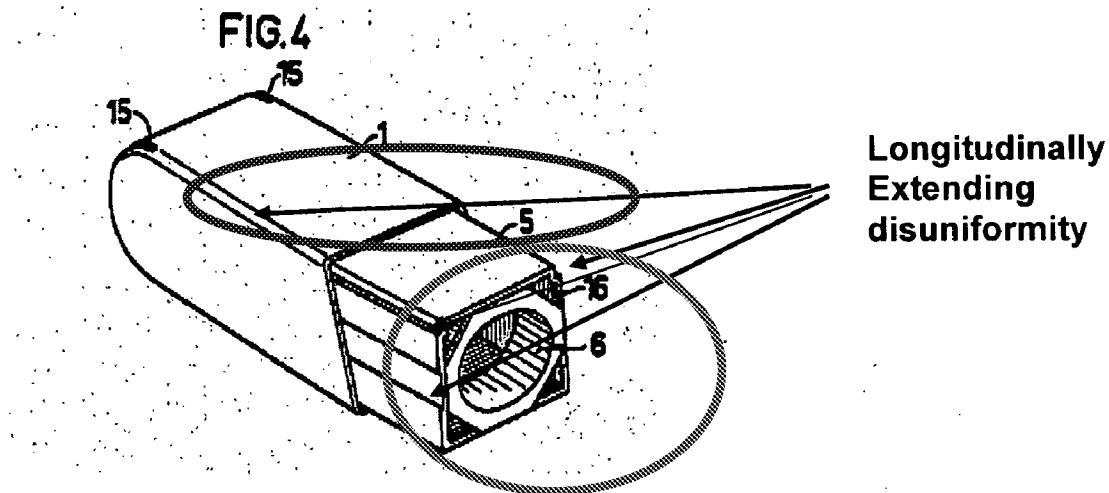
a container having the pharmaceutical formulation comprising at least one medicament present therein; and

a mouthpiece configured for oral engagement with a patient and in communication with said container, the mouthpiece having an inner surface and an outer surface;

wherein the outer surface of the mouthpiece contains at least one longitudinally-extending disuniformity such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient.

(Emphasis added). Applicants respectfully submit that Mono neither discloses nor suggests an oral inhaler as recited in claim 1.

The Office Action includes a copy of Figure 4 from Mono and points to several places on the figure as representing longitudinally-extending disuniformities. A copy of the Figure 4 with its annotations from the Office Action is provided here:



**Copy of Figure 4 from Mono (with annotations) contained in Office Action**

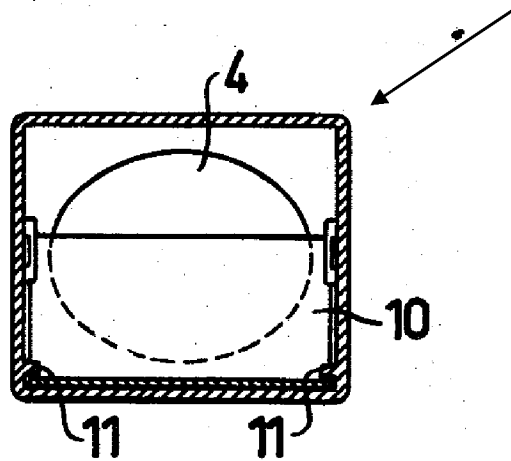
The portions of the Mono device highlighted in the Office Action and circled in red above are on the inner chamber part 5 and would not be contacted by the oral cavity of the patient. Thus, even if they were to provide longitudinally-extending disuniformities, they do not provide a longitudinally-extending disuniformity “such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient” as recited in claim 1.

Similarly, even though it is on the outer chamber part 2, the portion of the Mono device highlighted in the Office Action and circled in blue above would not be contacted by the oral cavity of the patient. As described in Mono at column 2, lines 11-16:

With this embodiment of the invention it is further possible to design the device in such a manner that the outlet opening may be tightly connected to the patient’s mouth without requiring the patient’s lips to be closed around the projecting mouthpiece as being required in prior art inhalation tubes.

Even if one were to argue that the portion of the Mono device highlighted in the Office Action and circled in blue above were contacted by the oral cavity of the patient, it is clear from Figure 2 of Mono, shown below, that the portion highlighted by the Office Action is a rounded corner, and thus is not a longitudinally-extending disuniformity.

**FIG. 2**



Thus, the portion of the Mono device highlighted by the Office Action and circled in blue above does not provide a longitudinally-extending disuniformity “such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient” as recited in claim 1.

For at least the foregoing reasons, Applicant respectfully submits that claim 1 is patentable over Mono and requests that this rejection be withdrawn. For similar reasons, Applicant respectfully submits that claim 27 is patentable over Mono and requests that this rejection be withdrawn.

Claims 2-5, 7-13, and 28 each depend from patentable independent claim 1. For at least this reason and without acquiescing in the Action’s rejections of these claims, Applicant respectfully submits that these dependent claims are also patentable and requests that these rejections be withdrawn. Applicant expressly reserves the right to argue the separate patentability of one or more of these dependent claims at a future date.

## **II. Section 103(a) Rejections Overcome**

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Mono. Applicant respectfully traverses this rejection.

Claim 6 depends from patentable independent claim 1. For at least this reason and without acquiescing in the Action's rejection of this claim, Applicant respectfully submits that this dependent claim is also patentable and requests that this rejection be withdrawn. Applicant expressly reserves the right to argue the separate patentability of this dependent claim at a future date.

Claims 14-26 and 29-34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Mono in view of U.S. Patent No. 6,474,331 (Rand). Applicant respectfully traverses these rejections.

Claims 14-26 and 29-34 each depend from patentable independent claim 1. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicant respectfully submits that these dependent claims are also patentable and requests that these rejections be withdrawn. Applicant expressly reserves the right to argue the separate patentability of one or more of these dependent claims at a future date.

## **III. Conclusion**

All claim rejections being addressed in full, Applicant respectfully requests the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance. Should the Examiner have any questions regarding the foregoing, Applicant respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-9024.

Respectfully submitted:

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